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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,060	02/12/2002	David Mu	38002-0024	2406

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/173,060	KANEKO ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-38 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 9-14, 22-24, and 33-35, drawn to a method for diagnosing a cancer in a mammal, comprising detecting and measuring the hepsin gene copy number in a subject, classifiable in class 435, subclass 5.

II. Claims 4-8, drawn to a method for inhibiting cancer in a mammalian tissue, comprising contacting the tissue with a nucleotide molecule that inhibits hepsin gene function, classifiable in class 435, subclass 6.

III. Claim 17, drawn to a method for inhibiting cancer in a mammalian tissue, comprising contacting the tissue with a inhibitor of hepsin protein, wherein the inhibitor is an antibody, classifiable in class 435, subclass 7.24.

IV. Claim 20, drawn to a method for inhibiting cancer in a mammalian tissue, comprising contacting the tissue with a inhibitor of hepsin protein, wherein the inhibitor is a small molecule, classifiable in class 435, subclass 6.

V. Claims 25-31, drawn to an isolated hepsin gene amplicon, wherein the amplicon comprises more than one copy of a polynucleotide, classifiable in class 536, subclass 23.1.

VI. Claim 32, drawn to a method of making a pharmaceutical composition comprising identifying a compound, which is a modulator of hepsin, classifiable in class 435, subclass 5.

VII. Claim 37, drawn to a method of modulating hepsin activities by contacting a subject with a modulator of hepsin protein, wherein the modulator is a small molecule, classifiable in class 435, subclass 7.24.

Claims 15, 16, 18, 19, 21, 36 and 38 links patentably distinct inventions of Groups II-IV and VII. The restriction between the linked inventions is subject to the nonallowance of the linking claims 15, 16, 18, 19, 21, 36 and 38.

Upon the allowance of the linking claim(s), the restriction as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The above inventions are distinct, each from the other because of the following reasons:

Although the methods of Groups II-IV are related because they encompass a method for inhibiting cancer in a mammalian tissue, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches

of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the nucleotide molecule that inhibits hepsin gene function Group II, would not encompass all of the art relevant to the antibody inhibitor of hepsin protein of Group III or the small molecule inhibitor of hepsin protein of Group IV. They are materially distinct methods, which differ in method steps, reagents and/or dosages and/or schedules used, and response variables. Thus, they are patentably distinct from each other.

Inventions of Groups I and II-IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group I is drawn to a method for diagnosing a cancer in a mammal, comprising detecting and measuring the hepsin gene copy number in a subject, and is thus materially different from the methods of for inhibiting cancer in a mammalian tissue of Groups II-IV. The steps required in the method of Group I would be materially different and are not required of Groups II-IV, and a search and examination of these methods in one patent application would result in an undue burden, since the searches for the methods are not eco-extensive, the classification is different, and the subject matter and steps are divergent. Thus, they are patentably distinct from each other.

The invention of Group V is related to the method invention of Group II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used

in materially different processes of use. For example, the isolated hepsin gene amplicon of Group V can be used as a hybridization probe to identify hepsin gene expression, which is a materially different process than a method for inhibiting cancer in a mammalian tissue, comprising contacting the tissue with a nucleotide molecule that inhibits hepsin gene function, as in Group II.

The invention of Group VI appears constitutes a patentably distinct invention from all other Groups because the invention of Group VI is drawn to a method of making a pharmaceutical composition comprising identifying a compound which is a modulator of hepsin which comprises identifying and synthesizing a compound, which is a step that is unique to this Group, and thus requires assays to determine a compound which is a modulator of hepsin, along with necessary analyses, which are steps not found in any other Group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject mater, and separate search requirements, it would be unduly burdensome for the Examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
September 24, 2003

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER